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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,463	10/30/2003	Kevin S. Marchitto	D6323D	7989

7590 07/12/2006

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EXAMINER

HANLEY, SUSAN MARIE

ART UNIT PAPER NUMBER

1651

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/697,463	Applicant(s) MARCHITTO ET AL.	
	Examiner Susan Hanley	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 3,7,8 and 12-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,9-11,19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the specie comprising molecules that reach a transition state in a biochemical reaction in an enzyme linked immunoassay with electromagnetic energy in the range of 200-20,000 nm in the reply filed on 4/21/06 is acknowledged.

Claims 3, 7, 8 and 12-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 4/21/06.

Claims 1, 2, 4-6, 9-11, 19 and 20 are presented for examination.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: it is not present in the application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 6, 9-11, 19 and 20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sherman et al. (1973) in light of Rawn (1983)

Sherman et al. disclose the effect of electromagnetic radiation on the rate of an enzyme reaction. Lactate dehydrogenase (LDH) was reacted with irradiated pyruvate. The rate of the

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reaction was significantly increased. The disclosure of an enzyme-catalyzed reaction meets the limitation of instant claim 20. The substrate was irradiated with light at a wavelength of 546 nm (bottom of p. 50) which falls within the wavelength range of instant claim 6. Light is electromagnetic energy, as in instant claim 5. Sherman et al. disclose that the electromagnetic radiation causes the substrate to achieve a new physical state S^* . Sherman et al. report that the V_{max} (rate) for the reaction increased compared to the non-irradiated control. The K_m value for the irradiated reaction decreased significantly compared to the non-irradiated control (see the double-reciprocal plot in Fig. 1, p. 56). The ratio of The decrease of the K_m concentration indicates that less substrate was required to obtain $\frac{1}{2}$ the maximal reaction rate. The decrease in K_m indicates a structural change in the S^* state compared to the non-irradiated state S such that the LDH is able to recognize and bind the S^* state more easily to produce an $E-S^*$ transition state compared to the non-irradiated substrate (See the discussion by the supporting reference on p. 231-233 of Rawn). Thus, the disclosure by Sherman et al. meets the limitations of instant claims 1 and 2 because the substrate of an enzymatic reaction is irradiated to increase its energy state to S^* and the rate of the reaction is increased, as in instant claim 1. The change in the K_m value for the irradiated substrate compared to the non-irradiated substrate demonstrates that the S^* physical state of the substrate is different than S for the non-irradiated reaction, as in instant claim 10. The binding of the S^* physical state by the enzyme inherently stabilizes the S^* physical state to produce an $E-S^*$ complex, as in instant claims 2, 11 and 19.

Although Sherman et al. do not expressly state that the change in molecular state of the irradiated substrate is due to vibrations or molecular rotation, such alteration is inherent to the process. Irradiation of a molecule causes an increase in the energy state of a molecule because the molecule absorbs the energy and transfers some of the energy to the bonds which causes an increase in the vibrational and/or rotational state of the molecule.

The disclosure by Rawn is a supporting reference and properly used in a rejection under of U.S.C. 102 since it describes the basic enzyme kinetics. MPEP 2131.01.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 16, 18, and 22 of copending Application No. 10/739,680. Although the conflicting claims are not identical, they are not patentably distinct from each other because the independent claims of both applications is drawn to the same steps wherein the reactants for a biochemical reaction are subjected to electromagnetic radiation which causes an increase in the rate of the biochemical reaction. Claims 16 and 18 of '680 are species for the claimed genus of biochemical reactions. Claim 22 of '680 corresponds to the enzyme linked immunoassay reaction of instant claim 4.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 2 and 4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 41, 44 and 45 of copending Application No. 10/774,320. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 1 and claim 41 of '320 are drawn to the same steps wherein

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the reactants for a biochemical reaction are subjected to electromagnetic radiation which causes an increase in the rate of the biochemical reaction. Claim 42 of '320 corresponds to instant claim 2 regarding increasing the energy of the reactants. Claims 44 of '320 is a specie for the claimed genus of biochemical reactions. Claim 45 of '320 corresponds to the enzyme linked immunoassay reaction of instant claim 4.

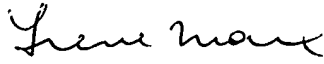
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan Hanley
Patent Examiner
1651


IRENE MARX
PRIMARY EXAMINER